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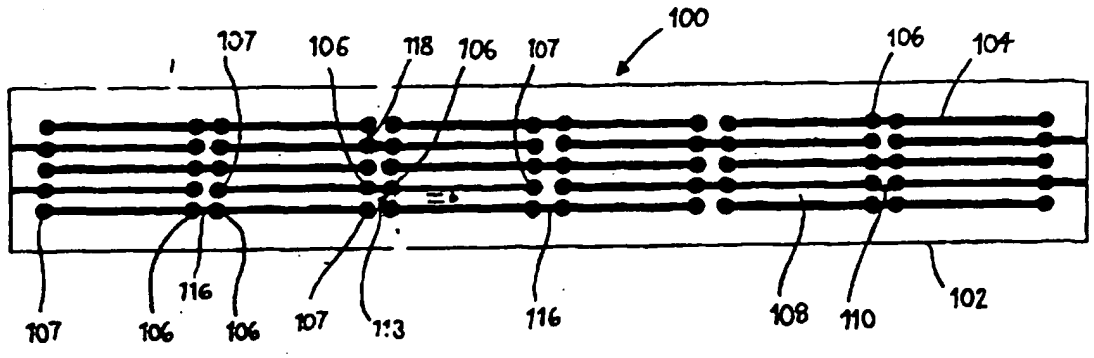

(57) Abstract

An expandable stent for a tubular (e.g. vascular) graft or prosthesis or for expanding or supporting a body passageway comprises a thin walled tubular member (102) having slots (104) defining a plurality of interconnected elongate members (108) arranged such that the application of a distributed radially-outward force within the tubular member expands it radially by deformation thereof, so as to open-out the slots, characterised by means (106, 107) defining relatively weak portions (118) of locally-reduced cross section which upon expansion of the stent act as plastic hinges and in which said deformation is concentrated.

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EXPANDABLE SURGICAL STENT

This invention relates to expandable surgical stents for use with vascular grafts or protheses or for the expansion and/or support of a blood vessel or other body passageway.

The surgical process of expandable intraluminal vascular grafting involves the insertion of a vascular graft into a blood vessel. The graft is in the form of a fabric tube eg. of TEFLON® or DACRON® having attached thereto an expandable stent enabling it to be attached to a healthy portion of blood vessel. The graft is manoeuvred using a balloon catheter to the desired position in the vessel, where the stent is expanded outwardly by inflating the balloon to abut the inner surface of the vessel, thereby holding the graft in place. This procedure is common for example in the treatment of blocked arteries, where, after opening the artery, the walls of the artery require internal support to prevent collapse; for the treatment of aortic and other aneurysms; and for the supportive reinforcement of constricted portions of the oesophagus, intestine and ureter, or other hollow viscera.

Such stents may take a variety of different forms, such as helically wound coils, and expandable structures of wires or bars. A known surgical stent is disclosed in EP-A-0 221 570, and is shown in Figure 1 hereof. The stent 70 comprises a thin-walled tube 71 in which a plurality of slots 82 are formed. The slots 82 are of uniform length and are arranged both parallel to the longitudinal axis of the tubular member 71 and circumferentially, thereby forming elongate members 75 in the wall 74 of the tubular member 71. Each slot has ends bounded by members 77, which connect adjacent elongate members 75.

The tube 71 has a first diameter *d* that permits the stent 70 to be inserted into the blood vessel or body passage. When in position, the stent 70 may be expanded by applying

a radially outward force to the walls of the stent. This is achieved by inflating a balloon portion of a catheter situated along the longitudinal axis of the stent. The stent expands to a diameter d' so that the walls of the stent come into contact with the inner walls of the blood vessel. The increase in the diameter of the stent is determined by controlling the volumetric expansion of the balloon portion of the catheter. Following the required inflation of the balloon, the balloon is deflated and the catheter removed, leaving the expanded stent in position.

A problem that has been encountered in using the above stents occurs when there is any variation in the cross-section of the elongate members 75 or connecting members 77. Should a portion of one of such members have a enlarged cross-section, for example, it will be more resistant to bending (i.e. it will be stiffer), and so will undergo a smaller radial expansion than the remainder of the wall of the stent for a particular balloon pressure. Small manufacturing irregularities in the initial unexpanded geometry of the stent can therefore produce significant irregularities in the final expanded form, compromising its effectiveness for purpose. Because the bending resistance is proportional to the square of the member width, the effect of small imperfections is magnified. The stent can therefore dilate under internal balloon pressure in a haphazard and inconsistent manner. Such behaviour is surgically highly undesirable. It is therefore critical that the fabrication process for the prior art stents is such that the lattice of members 75, 77 are of very closely uniform cross-section. This is both difficult and expensive.

It is an object of at least the preferred embodiments of the present invention to provide an expandable stent that offers consistent expansion characteristics, leading to greater control over the final expanded shape of the stent, and repeatability in production.

Accordingly, in one aspect the present invention provides an expandable stent for a tubular (eg. vascular) graft or prosthesis or for expanding or supporting a body passageway, said stent comprising a thin walled tubular member having slots defining a plurality of interconnected elongate members arranged such that the application of a distributed radially-outward force within the tubular member expands it radially by deformation thereof, so as to open-out the slots, characterised by means defining relatively weak portions of locally-reduced cross section which upon expansion of the stent act as plastic hinges and in which said deformation is concentrated.

Preferably, the relatively weak portions are at the ends of the elongate members.

The relatively weak portions are defined by relatively enlarged regions of adjacent slots.

In another aspect the invention provides an expandable stent for a tubular (eg. vascular) graft or prosthesis or for expanding or supporting a body passageway, said stent comprising a thin walled tubular member having therein a plurality of slots distributed circumferentially and longitudinally of said tube, characterised in that at least some of the slots have at least one locally-enlarged region, said regions defining an array of relatively weak portions in said tubular member whereby, on expanding said stent, said portions act as plastic hinges.

Preferably, at least some of the slots have a pair of separate locally-enlarged regions, each one of the pair being situated equidistant from the centre of the slot, for example at the ends of the slots.

Advantageously, at least some of the slots have a further pair of locally enlarged regions, each locally enlarged region of said further pair being situated equidistant from the centre of the slot. Each of one pair of locally enlarged regions situated in one slot is

preferably aligned axially of the stent with one of the further pair of locally enlarged regions situated in a circumferentially adjacent slot.

A locally enlarged region may be formed by a round hole of diameter greater than the width of the slot.

Preferably. the material between unenlarged regions of circumferentially adjacent slots remains substantially undeformed during expansion of the tubular member.

In both of the above aspects of the present invention. the slots may be equally circumferentially spaced around the tube, and preferably in a staggered relationship. The slots may be formed by mechanical cutting or by electro-discharge machining.

Preferably, the plurality of slots each have a first and a second end and the first ends of alternate circumferentially spaced slots are contained within the same radial plane perpendicular to the longitudinal axis of the tube.

In another aspect the invention provides a tubular graft or prosthesis comprising at least one stent as set forth above.

The invention will now be described with reference to the accompanying drawings in which:-

Figure 1A is a perspective view of an expandable intraluminal stent according to the prior art.

Figure 1B is a perspective view of the stent according to Figure 1A in expanded form.

Figure 2 is a plan view of the expandable intraluminal stent according to the present invention which. for greater clarity, does not show all of the slots formed in the wall of the tube. Such slots as are shown are in a plane development so that their relative positions can be seen.

Figure 3 is a cross-section perpendicular to the longitudinal axis of the stent according to the present invention.

Referring to Figure 2, stent 100 comprises a seamless tubular member 102. The member is preferably of uniform thickness, for example 250 μm thick, and may be formed from medical grade stainless steel, for example 316L. When for use in repair of an aortic aneurysm the stent has a length of typically 40 to 50mm, and a diameter of 5mm.

A plurality of slots 104 are provided within the member 102, thereby forming a plurality of elongate members 108 in the tubular member 102 that are joined by interconnections 110. The slots may be formed by a variety of different conventional methods, such as mechanical or laser cutting, electro-discharge machining or electro-chemical machining, exposed edges being rounded or otherwise deburred and blunted to avoid presenting a sharp edge which may injure or irritate body tissue during insertion or subsequent use. For example, for a stent 40mm long and 5mm in diameter, the length of each slot is preferably 9mm, and the width of the slot is preferably less than 200μm. The slots 104 are distributed both longitudinally and circumferentially of the tubular member. In this example, the longitudinal spacing between the slots is 250 μm, and the circumferential spacing between adjacent slots is such that there is an angular pitch of 15° between the centres of the slots, as shown in Figure 3. Circumferentially spaced adjacent slots may also be arranged in a staggered relationship, as shown in Figure 2 where, in this example, the ends of alternate circumferentially spaced slots are contained within the same radial plane perpendicular to the longitudinal axis of the tubular member.

First 106 and second 107 pairs of locally-enlarged regions are formed in each of the slots 104, thereby forming portions of locally reduced cross-section 118 in the elongate members 108. This is the preferred arrangement, but the invention is not limited to this

particular number of locally-enlarged regions 106, 107. The locally-enlarged regions 106, 107 preferably take the form of round holes of diameter greater than the width of the slot and preferably at least twice as wide. For example, for a slot width of 200 μm or less. the diameter of the hole may be 400 μm. In the preferred embodiment shown in Figure 2, each slot 104 contains two pairs of holes 106 and 107. The holes of each pair are situated equidistant from centre 116 of the slot. One pair, 107, is situated at the ends of the slots, whereas each of the other pair 106 is situated so as to be aligned axially of the stent with one of the pair of holes 107 in the circumferentially adjacent slot. With this configuration, the cross-section of the portions 118 are substantially reduced in comparison with the cross-section of material between unenlarged regions of the slots 104 of the stent. In this example, the width b of portion 118 is 253μm ± 10μm, compared to a width of approximately 0.45mm for the major portion of the elongate members 108. For the stent to have consistent expansion characteristics, it is important that the dimension b is accurately controlled. Thus the positions and diameter of the holes 106,107 is subject to a close tolerance, but the width of the major part of the elongate members may be subject to a wider tolerance. In this example the holes are nominally 400μm diameter, spaced longitudinally at 4.15mm centres and at 15° intervals circumferentially.

In operation, the stent 100 is expanded by inflating a balloon portion of a catheter placed within the stent substantially along the longitudinal axis of the stent 100. When the balloon comes into contact with the inner walls of the stent, the balloon exerts a radially-outward force on the walls of the stent, causing the stent to radially expand by deformation so as to open-out the slots 104. Portions of the stent 118 having a reduced cross-section are relatively weak compared to the material between the unenlarged regions of the slots of the stent, and so are preferentially deformed by the balloon. Due to the concentration of the

deformation in the portions 118, the material of the members 108 between unenlarged regions of the slots remains substantially undeformed by the force acting on them by the expanding balloon. The portions 118 act as plastic hinges, permitting pivotal movement of the members 108 between the hinges as the diameter of the stent expands.

The relatively weak portions in the walls of the stent thus determine the expansion characteristics of the stent and its final shape. The final shape of the stent of the invention is therefore much more controlled than the final shape of known stents not provided with defined points of weakness, thereby providing a significant improvement in the safety of vascular grafting or prostheses operations with the final shape of the stent, and its expansion behaviour, being much more consistent and reliable. The size and location of the holes 106, 107 may be reliably controlled and repeatable in production of the stents, to the necessary degree of accuracy using known techniques. Because the resulting cross section of the plastic hinges 118 is markedly less than that of the members 108, the small tolerance which is required in forming the holes 106, 107 can be substantially relaxed when forming the connecting slots, thus easing demands on the manufacturing process.

The stents may be made in a variety of sizes of both length and diameter, with different stiffnesses and ratios of expanded to unexpanded diameter, depending on the intended use in each case. They may be used alone to expand and/or support occluded or weak blood vessels or other body passageways (hollow viscera) or may be used in combination with a tubular prosthesis or graft to anchor the ends of the prosthesis in healthy but spaced-apart portions of a duct (eg. the aorta) enabling an intervening weak or damaged portion of the duct to be bridged by the graft.

Each feature disclosed in this specification (which term includes the claims) and/or shown in the drawings may be incorporated in the invention independently of other disclosed and/or illustrated features.

SUMMARY

An expandable stent for a tubular (eg. vascular) graft or prosthesis or for expanding or supporting a body passageway comprises a thin walled tubular member (102) having slots (104) defining a plurality of interconnected elongate members (108) arranged such that the application of a distributed radially-outward force within the tubular member expands it radially by deformation thereof, so as to open-out the slots, characterised by means (106,107) defining relatively weak portions (118) of locally-reduced cross section which upon expansion of the stent act as plastic hinges and in which said deformation is concentrated.

CLAIMS

1. An expandable stent for a tubular graft or prosthesis or for expanding or supporting a body passageway, said stent comprising a thin walled tubular member having slots defining a plurality of interconnected elongate members arranged such that the application of a distributed radially-outward force within the tubular member expands it radially by deformation thereof, so as to open-out the slots, characterised by means defining relatively weak portions of locally-reduced cross section which upon expansion of the stent act as plastic hinges and in which said deformation is concentrated.

2. A stent as claimed in claim 1, wherein the relatively weak portions are at the ends of the elongate members.

3. A stent as claimed in claim 1 or claim 2, wherein the relatively weak portions are defined by relatively enlarged regions of adjacent slots.

4. An expandable stent for a tubular graft or prosthesis or for expanding or supporting a body passageway, said stent comprising a thin walled tubular member having therein a plurality of slots distributed circumferentially and longitudinally of said tube, characterised in that at least some of the slots have at least one locally-enlarged region, said regions defining an array of relatively weak portions in said tubular member whereby, on expanding said stent, said portions act as plastic hinges.

5. A stent as claimed in any preceding claim, wherein said slots are equally circumferentially spaced around the tube.

6. A stent as claimed in Claim 4 or Claim 5, wherein circumferentially spaced adjacent slots are arranged in a staggered relationship.

7. A stent as claimed in Claim 6, wherein the plurality of slots each have a first end and a second end and where the first ends of alternate circumferentially spaced slots are contained within the same radial plane perpendicular to the longitudinal axis of the tube.

8. A stent as claimed in Claim 4, wherein at least some of said slots have a pair of separate locally-enlarged regions, each one of said pair being situated equidistant from the centre of the slot.

9. A stent as claimed in Claim 8, wherein said pair of locally-enlarged regions are situated at the ends of the slots.

10. A stent as claimed in Claim 8 or Claim 9, wherein at least some of said slots have a further pair of locally-enlarged regions, each locally-enlarged region of said further pair being situated equidistant from the centre of the slot.

11. A stent as claimed in Claim 10, wherein each of one pair of locally-enlarged regions situated in one slot are aligned axially of the stent with one of the further pair of locally-enlarged regions situated in a circumferentially adjacent slot.

12. A stent as claimed in Claim 3 or Claim 4, wherein a said locally-enlarged region is formed by a round hole of diameter greater than the width of the slot.

13. A stent as claimed in any of the preceding claims, wherein said tubular member is of uniform wall thickness.

14. A stent as claimed in any of the preceding claims, wherein the slots are formed by mechanical cutting.

15. A stent as claimed in any one of Claims 1 to 12, wherein the slots are formed by electro-discharge machining.

16. A stent as claimed in Claim 4, wherein the material between unenlarged regions of circumferentially adjacent slots remains substantially undeformed during expansion of the tubular member.

17. A tubular graft or prosthesis including at least one stent as claimed in any preceding claim.

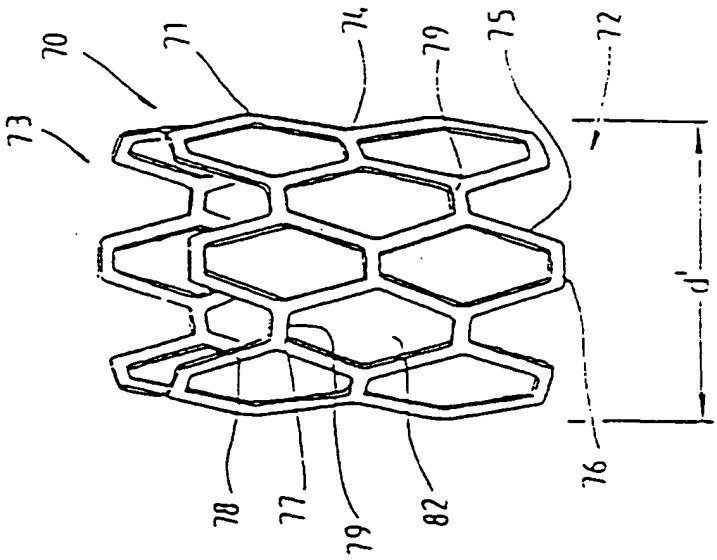

FIGURE 1B

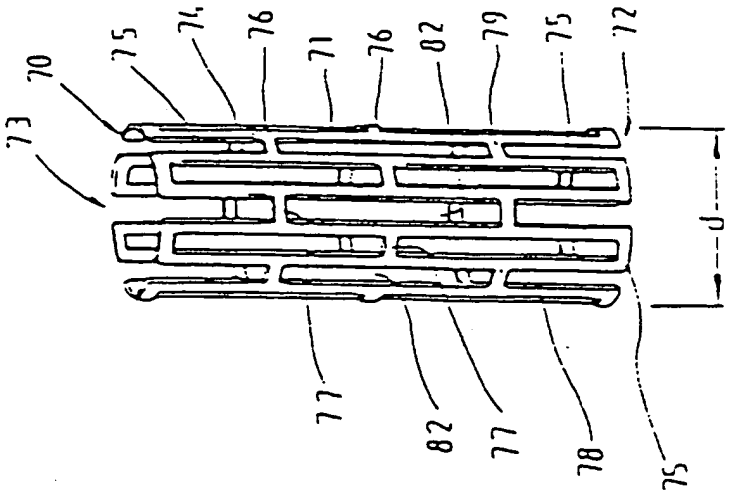

FIGURE 1A

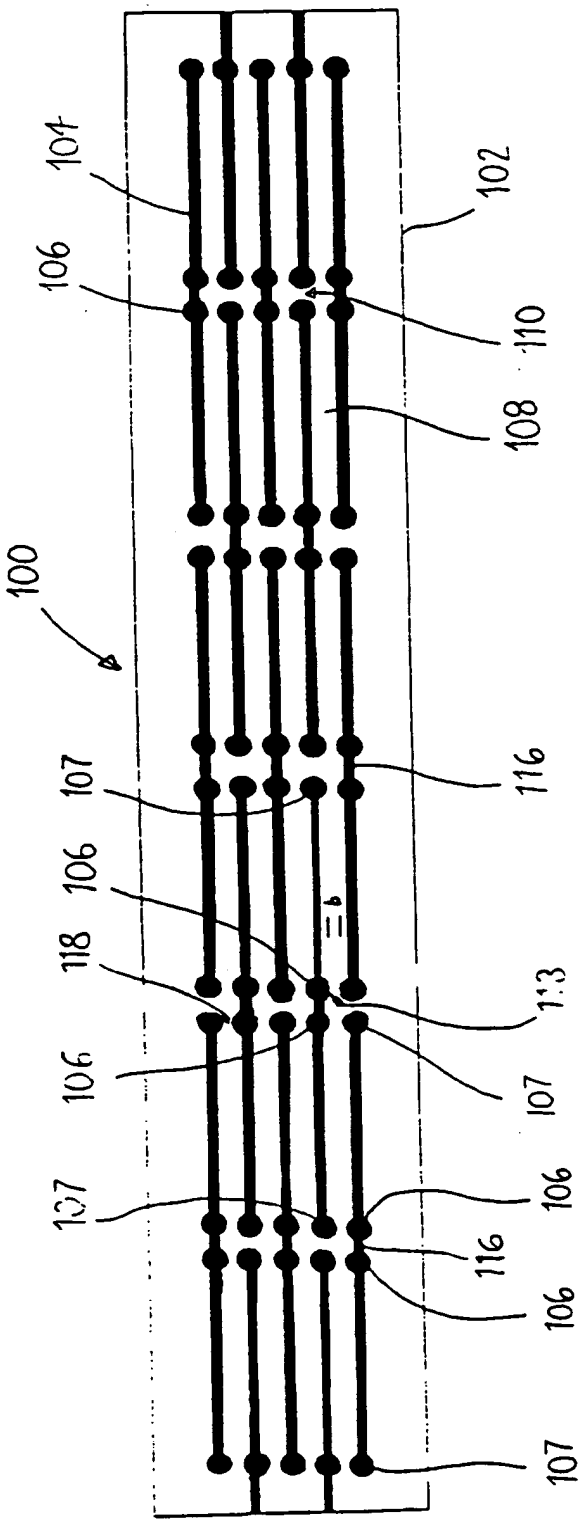
104
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FIGURE 2

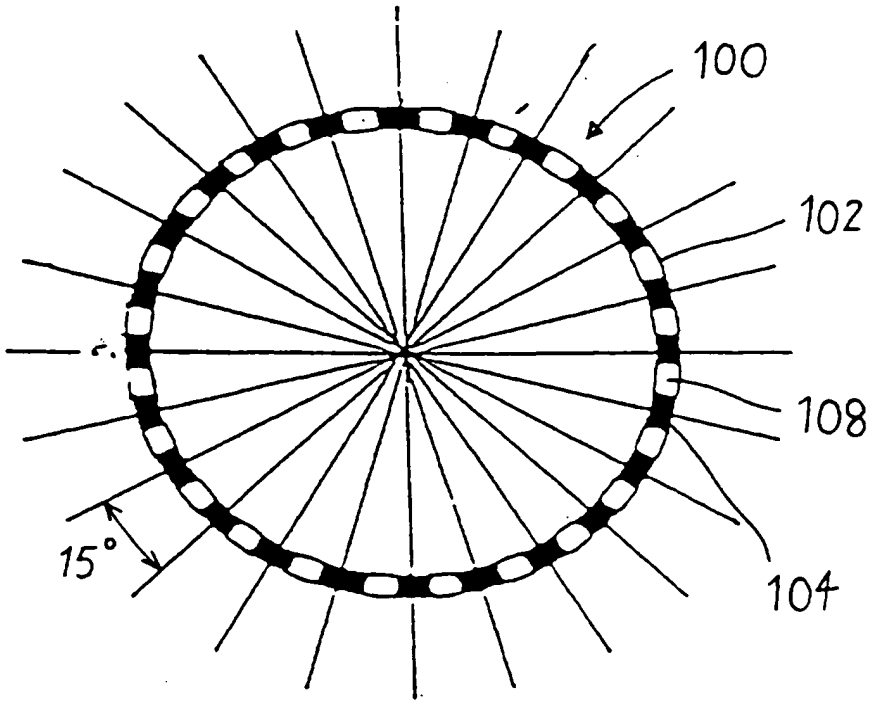

FIGURE 3

INTERNATIONAL SEARCH REPORT

Interna al Application No
PCT/GB 96/00676

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE,A,43 03 181 (ANGIOMED AG) 11 August 1994 see the whole document ---	1-5, 12-14, 16,17
X A	EP,A,0 566 807 (SGRO JEAN-CLAUDE) 27 October 1993 see figure 11 ---	1-4,8,9, 13,17 5
P,A	WO,A,95 09584 (GUERBET SA ;BOUDGHENE FRANK (FR); MICHEL JEAN BAPTISTE (FR); SAPOV) 13 April 1995 see page 4, line 16 - line 25; figures see page 10, line 35 - page 11, line 20 -----	1,3-5, 13,15,17

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☒ Patent family members are listed in annex.

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1

Date of the actual completion of the international search	Date of mailing of the international search report
5 July 1996	15.07.96
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